United States
Environmental Protection
Agency

Office of Prevention,
Pesticides
and Toxic Substances
(7501C)

PESTICIDE FACT SHEET

Name of Chemical(s): Kaolin
Reason for Issuance: Registration
Date Issued: ***March*** 1998
Fact Sheet Number:

1. DESCRIPTION OF THE PESTICIDE

Generic Names of the Active Ingredient:	Kaolin
OPP Chemical Code:	100104
Pesticide Types:	Repellent/ptotectant, aids in control of damage by insects, mites, fungi, and bacteria
U.S. Registrants:	Engelhard Corporation 101 Wood Avenue Iselin, NJ 08830

2. USE SITES

Kaolin is to be used as an aid in control of damage to plants from insects, mites, fungi, and bacteria. Kaolin is used at the rates of 6.25 to 12.4 lbs/acre for row crop vegetables, 25 to 175 lbs/acre for tree fruit crops, and 12.5 to 37.5 lbs/acre for small fruit crops. Treatments must coat all portions of plants including both sides of the leaves using standard spray equipments. Reapplication is normally required at 7 to 10 day intervals.

Sites*:* Beans (all), collards, garden beet, sugar beet, horseradish, radish, rutabagas, turnips, cotton, potato tomato, eggplant, pepper, lemons oranges, limes, apples, pears, loquats, crabapple, pears, quince, apricots, cherries, nectarines, peaches, plumes, prunes, blackberries, raspberries, dewberries and grapes.

3. SCIENCE FINDINGS

A. HUMAN HEALTH EFFECTS:

I. Toxicological Profile

The information submitted supports the lack of toxicity of kaolin based on its long history of use by humans without any indication of deleterious effects. Kaolin is a naturally occurring mineral found in huge deposits worldwide. It is used as an indirect food additive for paper / paper board dry food contact, adhesives, polymeric coatings, rubber articles, and cellophane. Kaolin is used as a cosmetic in face powders, face masks, and face packs. Kaolin is used in health products and toiletries, toothpaste, and antiperspirants. Kaolin can be used directly in foods as an anti-caking agent (up to 2.5%). Kaolin has GRAS (Generally Recognized a Safe) status under 21 CFR 186.1256 and is generally recognized as safe "As an indirect human food ingredient with no limitation other than current good manufacturing practice."

The overall toxicological risk from human exposure to kaolin is considered negligible. As a result, most mammalian toxicology studies were waived.

a. Acute Toxicity

The submitted toxicity studies are acceptable for these new registrations. No additional toxicity data are required. The data reported in the acute oral toxicity studies demonstrated that the acute oral LD_{50} for kaolin in rats is >5000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the acute dermal toxicity study demonstrated that the acute dermal LD_{50} for kaolin in rats is >5000 mg/kg of body weight. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV. The data reported in the primary eye irritation study demonstrate that the test substance was minimally irritating. Kaolin was not corrosive and all eye irritation effects cleared within 72 hours postdosing; Toxicity Category III. The data reported in the primary skin irritation study demonstrated that the test substance caused no dermal irritation in rabbits treated with 0.5 g kaolin for 4 hours. No toxicity or clinical abnormalities were observed throughout the study period; Toxicity Category IV.

b. Mutagenicity and Developmental Toxicity

Waivers for mutagenicity and developmental toxicity were requested. The Agency granted these waivers based on long use history of kaolin in food and food products without any indication of deleterious effects.

c. Subchronic Toxicity

Waivers for subchronic toxicity were requested. The waivers were granted based on the long use history of kaolin by humans without any indication of deleterious effects.

d. Chronic Exposure and Oncogenicity Assessment

Chronic exposure studies are conditionally required to support non-food uses only if the potential for adverse chronic effects are indicated based on 1) the subchronic effect levels established in Tier I subchronic oral, inhalation, or dermal studies, 2) the pesticide use pattern, or 3) the frequency and the level of repeated human exposure that is expected.

Oncogenicity studies are required to support non-food uses only if the active ingredient or any of its metabolites, degradation products, or impurities produce in Tier I studies morphologic effects in any organ that potentially could lead to neoplastic changes. The triggers for chronic exposure and oncogenicity studies were not met

e. Effects on the Immune and Endocrine Systems

Immunotoxicty studies and information on the endocrine effects of this compound were waived based on low exposure, lack of toxicity in the submitted exposure studies, and the long history of safe use of kaolin in food, pharmaceuticals and cosmetics.

II. Dose Response Assessment

No toxicological endpoints are identified.

III. Dietary Exposure and Risk Characterization

Dietary exposure of kaolin via food or water is difficult to estimate due to the widespread use of kaolin in thousands of products, in food, pharmaceuticals, cosmetics, in addition to use as an inert in pesticide formulations. Kaolin is an inert mineral and has no known toxicological effects. In the absence of any toxicological endpoints, risk from the consumption of residues in not expected for the general population including infants and children.

IV. Occupational, Residential, School and Day Care Exposure and Risk Characterization

No uses in residential areas are stated in proposed labels for kaolin. Therefore, humans exposure is not expected in these areas.

a. Occupational Exposure and Risk Characterization

There is a possibility for dermal, eye and inhalation exposure, but risk to applicators is mitigated as long as the product is used according to label directions. The Agency has considered kaolin in light of the safety factors in the Food Quality Protection Act (FQPA) of 1996 and has made a determination of reasonable certainty of no harm to the U. S. population in general, and to infants and children in particular.

b. Residential, School and Day Care Exposure and Risk Characterization

No indoor residential, school, or day care uses currently appear on proposed labels.

V. Drinking Water Exposure and Risk Characterization

Because of its insolubility in water, exposure to kaolin in drinking water is not expected.

VI. Acute and Chronic Dietary Risks for Sensitive Subpopulations Particularly Infants and Children

Dietary risk from exposure to kaolin is difficult to estimate due to the use of kaolin in thousands of products. Kaolin is an inert naturally occurring mineral, and it has no known toxicological effects. From its long history of use, there is no reported evidence or reason to believe that infants and children would be more sensitive to kaolin than adults.

VII. Aggregate Exposure from Multiple Routes Including Dermal, Oral, and Inhalation

Aggregate exposure would primarily occur in the mixer/loader/applicator subpopulation via dermal and inhalation routes. Risks associated with dermal and inhalation aggregate exposure are measured via the acute toxicity studies submitted to support registration. Because the inhalation toxicity studies for kaolin showed no toxicity (Toxicity Category IV), the risks anticipated for this route of exposure are considered minimal. Results of the acute dermal study indicated low toxicity (Toxicity Category IV), and no significant dermal irritation (Toxicity Category IV). Based on these results, the anticipated risks from dermal exposure are also considered minimal. Therefore, the risks from aggregate exposure via dermal and inhalation exposure are a compilation of two low risk exposure scenarios and are considered negligible.

VIII. Cumulative Effects

Kaolin is not toxic and therefore there would not be expected cumulative effects from common mechanisms of toxicity. In addition, kaolin is naturally occurring, and it is used in thousands of products. An exact cumulative exposure is not necessary due to the non-toxic nature of kaolin.

IX. Conclusion

Kaolin is considered as GRAS (Generally Recognized As Safe) by FDA under 21 CFR §186.1256. EPA has not identified any toxicity or clinical abnormalities. Moreover, the ecological effects studies demonstrated that there were no adverse effects. As a result, the Agency concludes that the exemption from the requirement of a tolerance is safe. Therefore, the tolerance exemption is established (63 FR 9427, February 25, 1998), to read as follows:

Section 180.1180 Kaolin; exemption from the requirement of tolerance.

Kaolin exempted from the requirement of a tolerance for residues when used on or in food commodities to aid in the control of insects, fungi, and bacteria (food/feed use).

B. ENVIRONMENTAL ASSESSMENT

I. Ecological Effects Hazard Assessment

Data waivers for avian acute and oral toxicity were requested and supported based on the current widespread agricultural use of kaolin clay as an inert, and the lack of reported avian toxicity incidents associated with this use. The submitted honeybee toxicity and spider monitoring studies are acceptable in support of these new registrations. No additional data are required. The data reported in the honeybee acute contact toxicity study demonstrated that there were no adverse effects resulting from treatment with kaolin. A single mortality observed in the kaolin-treated bees was unrelated to the treatment. The 48-hour LD_{50} was determined to be >100 µg kaolin/bee and the no effect dose was determined to be 100 µg kaolin/bee. The data reported in the honeybee acute dietary toxicity study demonstrated that there were no adverse effects resulting from treatment with kaolin in the diet. The few observed mortalities in the kaolin-treated bees were unrelated to treatment with kaolin. The dietary LC_{50} was estimated to be >1000 ppm kaolin, and the no observed effect concentration was estimated to be 1000 ppm kaolin.

The non-target insect/spider monitoring study in apple trees was inconclusive. The low and variable populations of predators (lady beetles, green lacewings, and spiders) precluded an assessment of the effects (if any) resulting from treatment with kaolin. However, based on data reported in companion studies on honey bees, it is not likely that kaolin treatment would cause any adverse effects in non-target predators. Furthermore, additional field monitoring studies with non-target insect/spiders will probably not provide any new information. The Agency does not require any additional data on non-target insects/spiders.

2. Environmental Fate and Ground Water Data

The need for environmental fate and groundwater data (Tier II) was not triggered under current requirements (40 CFR Section 158.690(d)(2)(vii through xv) because of practically non-toxic results indicated in Tier I studies. Risk to nontarget species is minimal due to the use pattern, application methods, and mitigation of nontarget aquatic organism toxicity with appropriate precautionary label statements under “Environmental Hazards.”

3. Ecological Exposure and Risk Characterization

A potential for exposure exists to nontarget insects, fish, and other wildlife with foliar spray applications.. However, test results indicate that the compound is practically nontoxic to birds and freshwater fish, and, at most, slightly toxic to aquatic invertebrates. BPPD also believes that low toxicity, and mitigating label language present minimal to nonexistent risk to wildlife.

ENVIRONMENTAL HAZARDS

Do not apply directly to water, to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwaters.

SUMMARY OF DATA GAPS :

There are no data gaps for the use of the compound kaolin.

5. CONTACT PERSON AT EPA **Office location / telephone / e-mail**

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DISCLAIMER: The information in this Pesticide Fact Sheet is a summary only and is not to be used to satisfy data requirements for pesticide registration and reregistration. Contact the Regulatory Action Leader listed above for further information.